

CLAIMS

1. A medicinal aerosol steroid solution formulation product with enhanced chemical stability, including:
  - 5 an aerosol container equipped with a dispensing valve and containing a medicinal aerosol formulation having a 20-ketosteroid drug dissolved therein; said 20-ketosteroid having an OH group at the C-17 or C-21 position or both, provided that said 20-ketosteroid is other than flunisolide; and
    - 10 wherein said container is provided with a non-metal interior surface so as to reduce chemical degradation of the 20-ketosteroid.
2. The product of claim 1, wherein said container is made of aluminum having an inert interior coating.
  - 15 3. The product of claim 2, wherein the interior coating is an epoxy-phenolic lacquer.
  4. The product of claim 1, wherein said dispensing valve is a metered dose valve.
- 20 5. The product of claim 1, wherein said medicinal aerosol formulation includes a hydrogen-containing propellant.
6. The product of claim 5, wherein the hydrogen-containing propellant is a hydrofluorocarbon.
  - 25 7. The product of claim 6, wherein the hydrofluorocarbon propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, and mixtures thereof.
- 30 8. The product of claim 1, wherein said medicinal aerosol formulation includes ethanol.

9. The product of claim 1, wherein said 20-ketosteroid has an OH group at the C-17 position, but not at the C-21 position.

10. The product of claim 1, wherein said 20-ketosteroid has an OH group at the C-21 position, but not at the C-17 position.

5 11. The product of claim 1, wherein said 20-ketosteroid has an OH group at both the C-17 and C-21 positions.

10 12. The product of claim 1, wherein the 20-ketosteroid is a corticosteroid selected from the group consisting of budesonide, triamcinolone acetonide, desonide, fluocinolone acetonide, alclometasone, beclomethasone, beclomethasone 17-monopropionate, betamethasone, betamethasone 17-valerate, clocortolone, desoximetasone, dexamethasone, dexamethasone sodium phosphate, dexamethasone 21-isonicotinate, diflorasone, flumethasone, methylprednisolone, 15 paramethasone, prednisolone, triamcinolone, clobetasol, and fluorometholone.

13. The product of claim 1, wherein the 20-ketosteroid is budesonide.

20 14. The product of claim 1, wherein the 20-ketosteroid is triamcinolone acetonide.

15. The product of claim 1, wherein the 20-ketosteroid is dexamethasone.

16. The product of claim 1, wherein the 20-ketosteroid is betamethasone 17-valerate.

25 17. The product of any preceeding claim wherein the container and/or the valve has a coating applied by vapor deposition.

18. The product of claim 17, wherein metal valve components have a coating applied by vapor deposition.

30 19. The product of claims 17 or 18, wherein the coating is a glass.

20. The product of claim 19, wherein the coating is applied by the Silcosteel process.

21. A method of reducing the chemical degradation of a medicinal 20-ketosteroid dissolved in a formulation contained in a metal container, said 20-ketosteroid being other than flunisolide and having an OH group at the C-17 position or C-21 position or both, comprising the step of providing a coating of inert material on the interior surface of the metal container so as to reduce reaction of the 20-ketosteroid with metal oxides from the container.

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22. A process for making a chemically stable steroid solution aerosol product by filling into a container an aerosol formulation comprising a dissolved 20-ketosteroid other than flunisolide, said 20-ketosteroid having an OH group at the C-17 position or C-21 position or both, and said container having an inert non-metal interior surface so as to avoid chemical degradation of the 20-ketosteroid due to interaction with the container.

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23. An aerosol valve having a non-metal coating applied to one or more metal surfaces by vapor deposition.

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24. The valve of claim 23 wherein the coating is fused silica.

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25. A medicinal aerosol product equipped with a metering valve and containing a medicinal aerosol formulation, said product comprising a layer of fused silica material applied on an internal surface of said product in contact with the formulation.

26. The product of claim 25, wherein said layer is on at least one component of the metering valve.

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27. The product of claim 25, wherein said layer is sub-micron in thickness.

28. A method of making an improved metered dose medicinal aerosol product containing a medicinal aerosol formulation, comprising the step of coating an internal surface of said product, that is to be in contact with the formulation, with a layer of fused silica.

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